UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,202	06/16/2006	David John Hampson	34141-US-PCT	2206

74479 7590 12/17/2007

Novartis Animal Health US Inc.
3200 Northline Avenue, Suite 300
Greensboro, NC 27408

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
12/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,202	HAMPSON ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,18,20,23,24 and 27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,18,20,23,24 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060616*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election of the inventions of Groups I and VII in the reply filed on November 1, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election with traverse of the species of SEQ ID NO:2 in the reply filed on November 1, 2007 is acknowledged. The traversal is on the ground(s) that searching all of the species would not be unduly burdensome. This is not found persuasive because each sequence will require separate sequence searches, which constitutes an undue burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

2. The Sequence Listing filed June 16, 2006 is approved.

3. The abstract of the disclosure is objected to because at line 2, "nucleotide" is misspelled. Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities: In the preliminary amendment to the specification filed June 6, 2006, line 1, "Phase" should be changed to "Stage", and the filing date of the PCT application needs to be corrected to read "December 17, 2004". A SEQ ID NO corresponding to the nucleotide sequence of Figure 3 needs to be inserted at page 8, line 3. Appropriate correction is required.

5. Claims 28-30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claims 28-30 embrace a wider range of polypeptides than does claim 27, upon which claims 28-30 depend, because claims 28-30 recite a less

stringent homology limitation. Because claims 28-30 embrace polypeptides not embraced by claim 27, claim 28-30 are improper dependent claims

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 18, 20, 23, 24, and 27-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising SEQ ID NO:2, methods of treating a disease associated with Brachyspira species using the same, and compositions comprising the same, does not reasonably provide enablement for polypeptides comprising fragments of SEQ ID NO:2, e.g., comprising SEQ ID NOS:4-6 and 8-22, for polypeptides which are homologues of SEQ ID NO:2 or of its fragments, or for methods of using the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of the invention is an isolated outer membrane protein of Brachyspira pilosicoli, fragments and/or homologues of the

same, and methods of using the protein, fragments, and/or homologues to treat diseases associated with Brachyspira species. With respect to (2), there have been few attempts to control infections by B. pilosicoli, and one previous attempt using a vaccine failed to provide protection. See Applicants' specification at page 2, lines 22-32. With respect to (3), the relative skill of those in the art is high. With respect to (4), the predictability of the therapeutic arts in general is low. In view of the failed attempt at vaccination discussed above, the predictability of treatment of Brachyspira infections in particular appears to be low. With respect to (5), the breadth of the claims is relatively large. The claims embrace polypeptides comprising any size fragments of the protein (Applicants' SEQ ID NOS:10, 16, and 22 consist of only six of the 564 amino acids present in the intact protein, and instant claims 1, 18, 20, 23, and 24 literally embrace fragments of these fragments), and embrace polypeptides comprising amino acid sequences which are as little as 60% homologous to Applicants' SEQ ID NOS:2, 4-6, and 8-22 (see instant claims 27-30). With respect to (6), Applicants have not identified the epitope and/or epitopes present in the protein of SEQ ID NO:2 which are necessary for successful treatment of diseases associated with Brachyspira species. No structure-activity relationship is disclosed in the specification. With respect to (7), the activity tests disclosed in the specification are limited to use of the intact 72 kDa protein. There is no disclosure of any testing of the fragments or homologues for activity in treating diseases associated with Brachyspira. With respect to (8), in view of the lack of predictability in the art, in view of the relative breadth of the claims, and in view of the lack of any disclosed structure-activity relationship and the lack of any disclosed testing of fragments or homologues of the intact protein, essentially random testing of all possible fragments and homologues would be necessary in order to determine activity and ability to treat diseases

involving Brachyspira activity. Such random testing constitutes undue experimentation. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

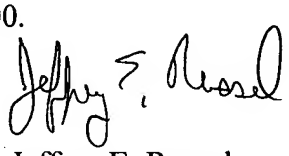
8. Claims 1, 18, 20, 24, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by the Tenaya et al article (J. Med. Microbiol., Vol. 47, pages 317-324) in view of Applicants' admission of the prior art at page 1, lines 20-21, of the specification. The Tenaya et al article teaches a 72 kDa outer envelope protein isolated from Serpulina pilosicoli. The protein is purified, combined with a carrier such as PBS and Freund's incomplete adjuvant, and administered to rabbits in order to raise antibodies. See, e.g., the Abstract; and page 319, column 2, first and second paragraphs. Applicants' specification at page 1, lines 20-21, shows that "Serpulina pilosicoli" and "Brachyspira pilosicoli" are synonyms. In view of the similarity in source, location within the bacteria, molecular weight, and antigenicity between the protein of the Tenaya et al article and Applicants' claimed polypeptide, the former is deemed to be the same as the latter, and the former inherently will have the same amino acid sequence as the latter. Sufficient evidence of similarity is deemed to be present between the protein of the Tenaya et al article and Applicants' claimed polypeptide to shift the burden to Applicants to provide evidence that the claimed polypeptide is unobviously different than the protein of the Tenaya et al article. Note that further characterization of a known protein, e.g., determination of

the protein's amino acid sequence, does not impart patentability to claims drawn to the known protein. Note also that because the protein of the Tenaya et al article is deemed inherently to comprise Applicants' SEQ ID NO:2, it will also inherently comprise fragments of Applicants' SEQ ID NO:2, i.e. it will comprise Applicants' SEQ ID NOS:4-6 and 8-22 and fragments thereof. Because the protein of the Tenaya et al article is administered to rabbits in which it acts as an antigen and raises antibodies, inherently the protein of the Tenaya et al article will vaccinate and prevent diseases including intestinal spirochaetosis in the rabbits to the same extent claimed by Applicants. Note that Applicants use the term "treatment" generically to encompass both prophylaxis and therapy of a disease. See, e.g., page 1, lines 7-9, of the specification. Again, sufficient evidence of similarity is deemed to be present between the method of the Tenaya et al article and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than the method of the Tenaya et al article.

9. The Trott et al article (animal Health Res. Rev., Vol. 2, pages 19-30) is cited to show the general state of the art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

December 10, 2007